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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,430	11/09/2000	Shuji Hanada	11151/5	5650

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EXAMINER

WILKINS III, HARRY D

ART UNIT	PAPER NUMBER
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1742

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DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,430

Applicant(s)

HANADA ET AL.

Examiner

Harry D Wilkins, III

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-3 and 8-27 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 9-11, 16-18, 20-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A).

Araya et al teach (see English abstract) that the alloy is composed of titanium, with niobium and tantalum and optionally tin. The alloy contains 20-60 wt% of niobium plus tantalum and less than 5 wt% tin. Araya et al teach (see English abstract) that it is desirable for the alloy to contain at least 15 wt% niobium and at least 6 wt% tantalum. Araya et al provide (see Table 1) specific examples of the alloy which contain 29 wt% niobium, 13 wt% tantalum and 4.6 wt% tin with the balance titanium. This alloy is equivalent to 20.3 at% niobium, 4.67 at% tantalum, 2.52 at% tin and 72.5 at% titanium. If the extreme lower limits of niobium and tantalum are used, along with the extreme upper limit of tin, the alloy would be 9.06 at% niobium, 1.86 at% tantalum, 2.36 at% tin and 86.72 at% titanium.

Though Araya et al fail to meet the claimed range of tin, the range taught by Araya et al is close enough to the presently claimed range that one of ordinary skill in

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the art would have expected the two alloys to have the same properties. See MPEP 2144.05.

With respect to the properties that the alloy has shape memory characteristics and has superelasticity at the human body temperature, the alloy composition taught by Araya et al is close enough to the alloy composition recited in the present claims, that one of ordinary skill in the art would have expected that the products taught by Araya et al would have the same shape memory characteristics and superelasticity as claimed.

Regarding claims 2 and 17, Araya et al teach that the alloy may contain 86.72 at% titanium. Though Araya et al fail to meet the claimed range of tin, the range taught by Araya et al is close enough to the presently claimed range that one of ordinary skill in the art would have expected the two alloys to have the same properties. See MPEP 2144.05.

Regarding claims 3 and 18, Araya et al teach, based on the extreme limits, that the alloy may contain a total of 10.92 at% niobium plus tantalum.

Regarding claims 9 and 20, Araya et al teach (see English abstract) that the alloy composition is useful as a dental root. Thus, the alloy would have inherently been used as an artificial dental implant.

Regarding claims 10, 16, 21 and 27, Araya et al teach (see English abstract) that the alloy composition is useful as an artificial joint. An arthrosis, as defined by Merriam Webster's Collegiate Dictionary, 10th Edition, is an articulation between bones. The same defines articulation as a joint or juncture between bones or cartilages in the skeleton. Thus, an artificial arthrosis is another way of saying artificial joint.

Regarding claims 11 and 22, Araya et al teach (see English abstract) that the alloy is useful as a substitutive material for bone.

4. Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claims 1 and 17 above, and further in view of Farzon-Nia et al (US 5,429,504).

As cited above, Araya et al do not teach that the alloy may be used to make orthodontic appliances.

Farzin-Nia et al teach (see col 2, lines 19-33) orthodontic applications for a titanium-base material which may contain tin and niobium.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make orthodontic appliances as taught by Farzin-Nia et al because the alloy of Araya et al is bio-compatible.

5. Claims 12 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claims 1 and 17 above, and further in view of Beyar et al (US 6,127,597).

As cited above, Araya et al do not teach that the alloy may be used to make bone fixators.

Beyar et al teach (see col 3, lines 16-25) that bone fixators have been known to be made of titanium or nitinol (a shape memory alloy).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a bone fixator as taught by Beyar et al because the alloy of Araya et al is bio-compatible and has high strength.

6. Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claims 1 and 17 above, and further in view of Regan (US 4,795,458).

As cited above, Araya et al do not teach that the alloy may be used to make thrombus inhibitors (i.e.-stents).

Regan teaches (see col 1 ,lines 51-53) that stents are well known to be made of nitinol, a shape memory alloy of nickel and titanium.

~~Therefore, it would have been obvious to one of ordinary skill in the art to have~~
used the alloy of Araya et al to make stents as taught by Regan because the alloy of Araya et al is bio-compatible and has shape memory characteristics.

7. Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claims 1 and 17 above, and further in view of Kizelshteyn et al (US 5,215,105).

As cited above, Araya et al do not teach that the alloy may be used to make catheter introducers.

Kizelshteyn et al teach (see col 3, lines 58-64) that it is well known in the art to make catheter introducers from shape memory alloys.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a catheter introducer as taught by Kizelshteyn et al because the alloy of Araya et al is bio-compatible and has shape memory characteristics.

8. Claims 15 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araya et al (JP 10-219375 A) as applied to claims 1 and 17 above, and further in view of Besselink et al (US 5,551,871).

As cited above, Araya et al do not teach that the alloy may be used to make a Harrington bar (i.e.-a device to correct scoliosis).

Besselink et al teach (see col 3, line 58 to col 4, line 22) that shape memory alloys, such as titanium-nickel-niobium, are useful as a scoliosis correction system ~~inside a patient's body where repeated adjustment is often not necessary or desirable~~ but stability is. A standard type of scoliosis correction is the use of a Harrington bar, as evidenced by Applicant's admission (see specification page 7, lines 4-6).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Araya et al to make a Harrington bar as taught by Besselink et al because the alloy of Araya et al is bio-compatible, has shape memory characteristics and has high strength.

Response to Arguments

9. Applicant's arguments filed 20 June 2003 have been fully considered but they are not persuasive. Applicant has argued that Araya et al teach directly away from the present invention and that the composition of Araya et al is not close enough to the presently claimed composition that one of ordinary skill in the art would have expected them to have the same properties, as per MPEP 2144.05.

In response to Applicant's argument, though Araya et al do not teach adding Sn at more than 2.5 at%, this value is still close enough to the presently claimed 3 at%, that

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one of ordinary skill in the art would have expected them to have the same properties. Though Araya et al teaches adding "Sn (tin) [at] not more than 5 wt%", there is no direct teaching against increasing the amount of Sn present, i.e.-Araya et al do not mention that if Sn is increased, the properties of the alloy will deteriorate. Thus, Araya et al does not contain a direct teaching away from the present invention.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-Th 10:00am-8:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III
Examiner
Art Unit 1742

hdw
July 29, 2003

ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700